2018 Current Fiscal Year Report: Psychopharmacologic Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Psychopharmacologic Drugs Advisory Committee	1009

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/04/2018	06/04/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 3 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 3

Meetings and Dates

Purpose	Start	End
The Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly to discuss new drug application (NDA) 209819, Sublocade (buprenorphine subcutaneous injection), submitted by Indivior Pharmaceuticals, Inc., for treatment of opioid dependence	10/31/2017	10/31/2017
The Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly to discuss new drug application (NDA) 210136, buprenorphine subcutaneous injection, submitted by Braeburn Pharmaceuticals, Inc., for treatment of opioid dependence.	11/01/2017	11/01/2017
The committee discussed new drug application (NDA) 209229, lofexidine hydrochloride, submitted by US WorldMeds, LLC, for mitigation of symptoms associated with opioid withdrawal and facilitation of completion of opioid discontinuation treatment.	03/27/2018	03/27/2018

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$7,334.00	$11,484.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$170,506.00	$173,228.00

18a(4). Personnel Pmts to Non-Member Consultants	$3,143.00	$5,468.00
18b(1). Travel and Per Diem to Non-Federal Members	$7,794.00	$9,669.00
18b(2). Travel and Per Diem to Federal Members	$3,668.00	$5,530.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$4,337.00	$3,626.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$51,927.00	$52,703.00
18d. Total	$248,709.00	$261,708.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investgational human drug products for use in the practice of psychiatry and other related fields and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in psychopharmacology, psychiatry, and epidemiology or statistics who are qualified by training and experience to evaluate scientific data. The committee has one technically qualified member identified with consumer interests. In addition to the voting members, the Committee includes one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee held three meetings during FY-18. On October 31, 2017, the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly to discuss new drug application (NDA) 209819, Sublocade (buprenorphine subcutaneous injection), submitted by Indivior Pharmaceuticals, Inc., for treatment of opioid dependence. Overall, the majority of the committee (18 to 1) agreed that the benefit and safety profile of buprenorphine was favorable for approval. The committee member voting “No”, expressed concerns over need for more data for safety. Regarding safety, the majority of the committee members (13 to 6) agreed that the safety data sufficiently supported the use of the proposed RBP 300 mg/300 mg dose regimen, even though the steady-state plasma exposures associated with RBP-6000 300 mg exceed those associated with the highest labeled dose of the reference product, Subutex. Those voting “Yes”, stated that it is necessary in clinical practice to go up on the dose of buprenorphine for effectiveness; the higher dose is needed for some patients with more severe opioid use disorders. Those committee members voting “No”, expressed concerns that they were unconvinced completely about the higher dose's added efficacy; they need to see more clinical safety data for the

highest dose; and more toxicology studies are warranted. Most the committee members agreed that both the RBP-6000 300/300 mg and 300/100 mg regimen are efficacious. Committee members stated they mostly see no significant difference in the doses with respect to efficacy given that there is no good evidence against it. The members further stated that the higher doses should include liver function monitoring. Most the committee members agreed with the need for the FDA proposed addition to the applicant's proposed REMS to include a one-time certification of health care settings that order and dispense RBP-6000 to put systems in place from being dispensed directly to the patient. Agency Action: The Agency is still reviewing all recommendations that were made at the meeting. On November 1, 2017, the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly to discuss new drug application (NDA) 210136, buprenorphine subcutaneous injection, submitted by Braeburn Pharmaceuticals, Inc., for treatment of opioid dependence. The majority of the committee members (17 members) recommended approval for some of the proposed doses. The committee members voting “C” (3 members) expressed concerns over the trial design being problematic and limited clinical data. The majority of the committee members (17 members) voted that the data from the clinical trial, taken together with the blockade study, provide substantial evidence of effectiveness of CAM2038 weekly and monthly formulations for the treatment of opioid use disorder in patients who are newly initiating buprenorphine treatment for some of the doses. Most of the committee members agreed that unsafe side effects were not observed with CAM2038. A few members commented that the clinical trial design mimics real world practice and is reflective of an effectiveness rather than efficacy trial, which should predict its success in treating opioid use disorders. However, other members disagreed and commented that the inherent design of the clinical trial, which did not allow for the collection of highly controlled data to predict the safety and efficacy of the CAM2038 doses investigated, was disappointing and a drawback. The majority of the committee members agreed and supported the need for the FDA's proposed addition to the REMS to include a one-time certification of health care settings that order and dispense CAM2038 to put systems in place from being dispensed directly to the patient. Some members commented that it may be too difficult to implement the REMS from a policy standpoint because of differences in State laws. The members also noted that the need for community pharmacists to be aware of patients use of CAM2038 via sharing of medication lists. Agency Action: The Agency is still reviewing all recommendations that were made at the meeting. On, February 14, 2018, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly to discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Charleston Laboratories, Inc., that contains hydrocodone, acetaminophen, and promethazine, for the short-term management of acute pain severe enough to require an

opioid analgesic while preventing and reducing opioid-induced nausea and vomiting. The committees discussed the abuse potential of this non-abuse-deterrent product and whether it should be approved. Agency Action: The Agency is still reviewing all recommendations that were made at the meeting. On March 27, 2018, the committee discussed the new drug application (NDA) 209229, lofexidine hydrochloride, submitted by US WorldMeds, LLC, for mitigation of symptoms associated with opioid withdrawal and facilitation of completion of opioid discontinuation treatment. The majority of the panel members (11 to 1) recommended approving this NDA application for mitigation of symptoms associated with opioid withdrawal but not for facilitation of completion of opioid discontinuation treatment. Additionally, most of the panel members agreed to the use of the 2.4 mg per day dose but not the 3.2 mg per day dose. One member voted “No” based on increased risks at the higher dose and limited safety data (with respect to duration of exposure) based on the trials. Agency Action: On May 16, 2018, the Agency approved LUCEMYRA (lofexidine) for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. It is expected that the committee will meet 2 to 4 times during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions, which helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientist on a full-time basis at a maximum rate of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

There are no reports required for this committee.

Designated Federal Officer

Kalyani Bhatt Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Conley, Robert	03/30/2016	10/31/2019	Global Development Leader, Pain and Core Therapeutics, Eli Lilly and Company	Representative Member
Dunn, Walter	06/30/2017	06/30/2021	Assistant Clinical Professor UCLA Dept of Psychiatry	Special Government Employee (SGE) Member
Fiedorowicz, Jess	06/28/2016	06/30/2019	Associate Professor, Departments of Psychiatry, Epidemiology and Internal Medicine, University of Iowa Carver College	Regular Government Employee (RGE) Member

Iyengar, Satish	07/01/2016	06/30/2020	Chair and Professor of Statistics, University of Pittsburgh	Special Government Employee (SGE) Member
Jain, Felipe	07/01/2017	06/30/2021	Assistant Clinical Professor University of California	Special Government Employee (SGE) Member
Jeffrey, Jessica	07/01/2016	06/30/2020	Assistant Clinical Professor, Associate Director, Division of Population Behavioral Health, UCLA	Special Government Employee (SGE) Member
Narendran, Rajesh	02/09/2016	06/30/2019	Attending Psychiatrist, Re:solve Crisis Network, Western Psychiatric Institute and Clinics	Special Government Employee (SGE) Member
Pickar, David	07/30/2014	06/30/2018	Adjunct Professor of Psychiatry, Johns Hopkins Medical School and the Uniformed Services University of Health Sciences	Special Government Employee (SGE) Member
Turner, Eric	07/01/2016	06/30/2020	Associate Professor Oregon Health & Science University	Regular Government Employee (RGE) Member
Wictzak, Kim	12/30/2015	06/30/2019	CONSUMER REPRESENTATIVE; Co-Founder, Executive Director, Woodymatters	Special Government Employee (SGE) Member

Number of Committee Members Listed: 10

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Psychopharmacologic Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓

Implementation of laws or regulatory requirements	☑
Other	☐

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

The utilization of the Psychopharmacologic Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; an to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

29

Number of Recommendations Comments

The committee made 29 recommendations from FY-03 through FY-18. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

79%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

7%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A